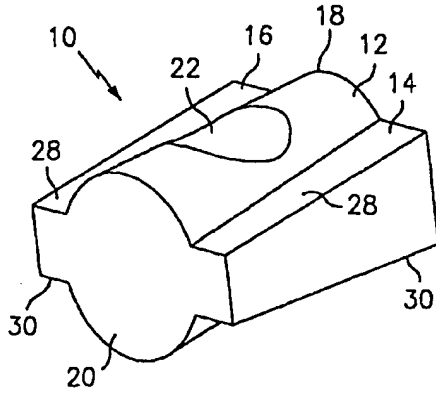


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(54) Title: <b>INTERVERTEBRAL IMPLANT</b>			
(57) Abstract <p>An intervertebral implant having a composite wedge/dowel configuration is provided. The intervertebral implant includes a central body portion and a pair of radially extending wings. The radially extending wings can be tapered from a first end of the implant to the second end of the implant along an axis parallel to the longitudinal axis of the central body portion. Alternately, the radially extending wings can be tapered along an axis transverse to the longitudinal axis of the cylindrical body portion or along any other axis between parallel and transverse to the longitudinal axis. A throughbore or plurality of throughbores extend from a top surface of the implant through the implant to a bottom surface of the implant. The implant may be formed from a cortical ring cut from the diaphysis of a long bone by milling the top and bottom surfaces of the cortical ring to form the substantially central body portion and the tapered radially extending wings. The cortical ring is milled such that the intramedullary canal of the cortical ring defines a throughbore in the central body portion of the implant. The sidewalls of the implant may be machined to form a substantially rectangular shape or the implant can be left to have a substantially circular configuration. Alternately, the implant may be formed of any biocompatible material having the requisite strength requirements via any known process, i.e., molding.</p>			
			

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## Description

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INTERVERTEBRAL IMPLANTBACKGROUND OF THE INVENTION

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5    1. Technical Field

          The present disclosure relates generally to intervertebral implants and, more particularly, to an intervertebral implant having a composite wedge/dowel configuration suitable for interbody spinal fusion.

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2. Background of Related Art

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          Intervertebral implants for fusing together adjacent vertebrae of a spinal column are well known in the surgical arts. Typically, a surgical procedure for implanting an intervertebral implant between adjacent vertebrae is performed to treat back pain in patients with ruptured or degenerated intervertebral discs, spondylolisthesis or other pathologies. A variety of different types of intervertebral implants have been developed for such a procedure including intervertebral wedge implants, spinal fusion cages and cylindrical threaded bone dowels.

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          A variety of different types of intervertebral implants have been developed to perform this function including spinal fusion cages, threaded bone dowels and stepped bone dowels. Exemplary implants are disclosed in U.S. Patent Applications filed on even date herewith, under Certificate of Express Mail Label Nos. EL260888076US and EL071686220US, and entitled "Ramp-Shaped Intervertebral Implant" and "Keyed Intervertebral Dowel", respectively, the entire disclosures of which are incorporated herein by reference.

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5 One fusion cage described in U.S. Patent No. 5,015,247 includes a  
cylindrical implant constructed from titanium having one closed end, one open end and  
a series of macro-sized openings formed through a side wall of the implant. The open  
10 end of the cylindrical implant is internally threaded and configured to receive a cap. A  
5 series of external threads are formed about the circumference of the cylindrical implant.  
Prior to use, a bone graft of cancellous bone taken from a patient's iliac crest is placed  
15 in a press and forced into the hollow body of the cylindrical implant such that  
cancellous bone extends through the macro-sized openings. The cap is then screwed  
20 onto the internally threaded end of the implant. Subsequently, the cylindrical implant is  
10 screwed into a previously prepared receiving bed between two adjacent vertebrae.

Because of their simplicity, spinal fusion cages are widely accepted.  
25 However, spinal fusion cages suffer from several drawbacks. For example, the  
cylindrical loading surface area of spinal fusion cages is small, thus two spinal fusion  
30 cages are typically required during a surgical procedure. Secondly, spinal fusion cages  
15 are made primarily from metal, most notably titanium. This material does not remodel  
but remains in a patient forever or until it is removed. Since vertebral bodies  
35 eventually fuse with the cancellous bone or other bone growth material positioned  
within the fusion cage, if removal is required, it can be very difficult and dangerous to  
40 the patient. Thirdly, spinal fusion cages do not maintain lordosis, thus the natural  
20 curvature of the spine is altered. Finally, it is difficult to insert a spinal fusion cage and

5 achieve equal purchase with the adjacent vertebrae. A spinal fusion cage will often  
tend to engage one vertebrae more securely than the other.

10 Wedge implants also suffer from several drawbacks. Although wedge  
implants have a greater load bearing surface area and are configured to maintain  
5 lordosis, wedge implants are more difficult to secure in place since they are not  
threaded into the vertebrae. Moreover, wedge implants have limited ability to prevent  
15 rotational forces between the two vertebrae that are intended to be fused.

Threaded bone dowels also suffer from some of the same drawbacks as  
20 spinal fusion cages. Threaded bone dowels have a small loading surface area and they  
do not maintain lordosis. Furthermore, threaded bone dowels are typically cut from  
10 bone with a hollow drill bit and subsequently are threaded. The hollow drill bit is  
positioned to cut transversely through the bone and the intramedullary canal during the  
25 cut. If the distance between the outer surface of the cut dowel and the intramedullary  
canal does not exceed a predetermined thickness, the dowel must be rejected. Since  
30 there is little bone to spare during such a transverse cut, a high percentage of bone  
dowels cut may be rejected due to anatomical variability between donors.

35 Accordingly, a need exists for an improved intervertebral implant which  
maintains simplicity for consistent surgical implantation, creates an improved  
40 biomechanical construct when implanted, maintains lordosis, conforms to vertebral  
endplates, spares the endplates in the load bearing region while perforating them in  
20 other areas to gain access to cells in cancellous bone; when produced from bone, can

5 remodel into bone, can be easily manufactured and addresses other problems associated with current spinal fusion implants.

### SUMMARY

10 In accordance with the present disclosure, an intervertebral implant

5 having a composite wedge/dowel configuration is provided. The intervertebral implant includes a central body portion and a pair of radially extending wings. The radially  
15 extending wings can be tapered from a first end of the implant to the second end of the implant along an axis parallel to the longitudinal axis of the cylindrical body portion for anterior or posterior insertion. Alternately, the radially extending wings can be tapered  
20 along an axis perpendicular to the longitudinal axis of the cylindrical body portion for lateral insertion or the wings can be tapered along any axis between axis parallel and perpendicular to the longitudinal axis of the implant. A throughbore or a plurality of throughbores extend from a top surface of the implant to a bottom surface of the  
25 implant providing a space for boney bridging to occur between the vertebrae which are intended to be fused. The throughbore(s) is dimensioned to receive growth factors including autograft, allograft, DBM, etc., to stimulate bone healing.

30 In a preferred embodiment, the implant is formed from a cortical ring allograft cut from the diaphysis or metaphysis of a long bone. The implant can be  
40 formed by milling the top and bottom surfaces of the cortical ring to form the central body portion and the tapered radially extending wings. The implant is milled such that  
20 the intramedullary canal of the cortical ring defines a throughbore in the central body

5 portion of the implant. Thereafter, the sidewalls of the implant may be machined to  
form a substantially rectangular shape or be maintained in an essentially semi-circular  
10 configuration. Alternately, the implant may be formed of any biocompatible material  
having the requisite strength requirements via any known process, i.e., molding,  
5 casting, machining, etc.

#### 15 BRIEF DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with reference to  
the drawings wherein:

20 FIG. 1 is a perspective view of one embodiment of the presently

10 disclosed intervertebral implant;

FIG. 2 is a side view of the intervertebral implant shown in FIG. 1;

25 FIG. 3 is a top view of the intervertebral implant shown in FIG. 1;

FIG. 4 is a front view of the intervertebral implant shown in FIG. 1;

30 FIG. 5 is a perspective view of another embodiment of the presently

15 disclosed intervertebral implant;

FIG. 6 is a side view of the intervertebral implant shown in FIG. 5;

35 FIG. 7 is a top view of the intervertebral implant shown in FIG. 5;

FIG. 8 is a front view of the intervertebral implant shown in FIG. 5;

40 FIG. 9 is a side view of a long bone;

20 FIG. 10 is a perspective view of a cortical ring cut from the long bone  
shown in FIG. 9;

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FIG. 11 is a side view of the cortical ring shown in FIG. 10;

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FIG. 12 is a perspective view of the cortical ring after the top surface has been milled;

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FIG. 13 is a perspective view of the cortical ring after the bottom surface has been milled;

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FIG. 14 is a perspective view of the cortical ring after the sidewalls have been machined;

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FIG. 15 is a perspective view of the cortical ring after the radially extending wings have been tapered;

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FIG. 16 is a perspective view of a third embodiment of the presently disclosed intervertebral implant;

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FIG. 17 is a perspective view of a fourth embodiment of the presently disclosed intervertebral implant;

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FIG. 18 is a perspective view of a fifth embodiment of the presently disclosed intervertebral implant;

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FIG. 18a is a perspective view of a variety of different shaped protrusions;

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FIG. 19 is a perspective view of a sixth embodiment of the presently disclosed intervertebral implant;

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FIG. 20 is a front view of the intervertebral implant shown in FIG. 19;

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FIG. 21 is a top view of the intervertebral implant shown in FIG. 19;

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FIG. 22 is a side view of the intervertebral implant shown in FIG. 19;

FIG. 23 is a perspective view of a seventh embodiment of the presently disclosed intervertebral implant;

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FIG. 24 is a side view of the intervertebral implant shown in FIG. 23;

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FIG. 25 is a front view of the intervertebral implant shown in FIG. 23;

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FIG. 26 is a top view of the intervertebral implant shown in FIG. 23;

FIG. 27 is a perspective view of an eighth embodiment of the presently disclosed intervertebral implant;

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FIG. 28 is a side view of the intervertebral implant shown in FIG. 27;

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FIG. 29 is a top view of the intervertebral implant shown in FIG. 27;

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FIG. 30 is a side view of the intervertebral implant shown in FIG. 27;

FIG. 31 is a top view of a pair of the intervertebral implants shown in FIG. 27 in their implanted positions;

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FIG. 32 is a perspective view of another embodiment of the

15 intervertebral implant;

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FIG. 33 is a perspective view of another embodiment of the intervertebral implant;

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FIG. 34 is a top view of the intervertebral implant shown in FIG. 33;

FIG. 35 is a front view of the intervertebral implant shown in FIG. 33;

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FIG. 36 is a side view of the intervertebral implant shown in FIG. 33;

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FIG. 37 is a front perspective view of another embodiment of the  
intervertebral implant; and

FIG. 38 is a side perspective view of the intervertebral implant shown in  
FIG. 37.

**DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS**

Preferred embodiments of the presently disclosed intervertebral implant  
will now be described in detail with reference to the drawings, in which like reference  
numerals designate identical or corresponding elements in each of the several views.

FIGS. 1-4 illustrate one preferred embodiment of the presently disclosed  
intervertebral implant shown generally as 10. Briefly, intervertebral implant 10  
includes a substantially cylindrical body portion 12 having a pair of radially extending  
wings 14 and 16. Cylindrical body portion 12 has a first end 18 and a second end 20.  
Each of radially extending wings 14 and 16 has a trapezoidal shape as viewed from the  
side of intervertebral implant 10.

Cylindrical body portion 10 includes a throughbore 22 which extends  
from a top surface 24 of body portion 12 to a bottom surface 26 of body portion 12.  
Throughbore 22 has a central axis which is perpendicular to the longitudinal axis of  
radially extending wings 14 and 16 and cylindrical body portion 10. Throughbore 22 is  
dimensioned to receive bone growth material including bone particles and/or a  
biocompatible osteoinductive or osteoconductive material. These materials may include  
cancellous bone, cancellous bone particles, ceramics, polymers, composites, BMP, etc.

5 Although not shown, additional bores may be formed through wings 14 and 16. These  
bores may also be packed with bone growth material.

10 Radially extending wings 14 and 16 each include an upper surface 28 and  
a lower surface 30. Surfaces 28 and 30 are tapered to converge toward each other from  
5 first end 18 of cylindrical body portion 12 to second end 20 of cylindrical body portion  
12, i.e., the height of the wings decreases from the first end to the second end of the  
15 implant. The wings are shaped in such a fashion as to conform to the vertebral end  
plates located above and below the implant. Implant 10 is suitable for anterior and  
20 posterior insertion. Alternately, surfaces 28 and 30 may be parallel to each other.

10 Intervertebral implant 10 can be constructed from a broad range of  
biocompatible materials, such as surgical stainless steel, titanium, ceramic  
25 hydroxyapatite, polymers, carbon fiber tantalum, etc., but is preferably constructed  
from cadaveric human or animal bone or bone composites. Such composites may  
30 include those discussed in U.S. Patent No. 5,899,939 to Boyce et al. and in U.S. Patent  
15 Application Serial No. 09/256,447 to Boyce et al., the entire disclosures of which are  
incorporated herein by reference. Intervertebral implant 10 can be used in cervical,  
35 thoracic and lumbar spinal fusion procedures. For cervical spinal fusion procedures, in  
which implants are typically between 8-15 mm in length and 10-14 mm in diameter,  
40 bone is preferably obtained from the fibula, radius, ulna or humerus. For thoracic and  
20 lumbar spinal fusion procedures in which implants are typically 10-30 mm in diameter  
and about 14-20 mm in height, bone is preferably obtained from the humerus, femur or

5 fashion, only the walls of the intramedullary canal and the circumferential surfaces of  
the bone may be demineralized. The strength imparting surfaces of the radially  
extending wings and the radial surface of the implant will not be compromised.

10 Moreover, the bone may be treated using a variety of bone healing enhancing  
5 technologies. For example, bone growth factors may be infused into the natural  
porosity of the bone and/or the bone may be infused with acid to further demineralize  
15 the bone. Both these bone treatments may be performed using the pressure flow system  
disclosed in U.S. Patent No. 5,846,484 which is incorporated herein by reference.

20 As discussed above, intervertebral implant 10 need not be formed from  
10 human cadaveric or animal bone but rather may be formed from any biocompatible  
material. As such, other known processes, such as molding, casting or machining  
25 techniques, may be used to manufacture the implant.

FIGS. 5-8 illustrate another embodiment of the intervertebral implant  
30 shown generally as 100. Intervertebral implant 100 is similar to intervertebral implant  
15 10 in that it includes a cylindrical body portion 112, a pair of radially extending wings  
114 and 116 and a throughbore 122 having a central axis which is perpendicular to the  
35 longitudinal axis of the radially extending wings and cylindrical body portion.  
However, radially extending wings 114 and 116 are tapered transversely such that wing  
40 116 has greater height than wing 114. Implant 100 is suitable for lateral intervertebral  
20 insertion.

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Intervertebral implant 100 may be manufactured using the same procedure as discussed above with respect to intervertebral implant 10 with slight variation in the milling step for forming the taper on the radially extending wings.

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Alternately, intervertebral implant 100 may be formed from a biocompatible material having the requisite strength requirements via any known process, i.e., molding, casting or machining.

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Referring to FIGS. 16-18, intervertebral implants 10 and 100 may include retaining structure for preventing the implant from migrating from an implanted position after implantation. For example, intervertebral implant 200 (FIG. 16) includes a plurality of triangular protrusions 202 formed on the tapered surfaces of the radially extending wings. Protrusions 202 engage the adjoining vertebrae and prevent the implant from movement in relation thereto. Alternately, the protrusions may assume a variety of different configurations. For example, ridge-shaped protrusions 204 (FIG. 17) or spherically-shaped protrusions 206 (FIG. 18) may also be provided.

Perforations (not shown) for receiving bone growth material may also be provided on the outer surface of the implant. It is noted that such protrusions or perforations may also be provided on the cylindrical body portion of the intervertebral implant.

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FIGS. 19-22 illustrate an alternate embodiment of the presently disclosed intervertebral implant shown generally as 300. Intervertebral implant 300 includes a substantially cylindrical body portion 312 having a pair of radially extending wings 314 and 316. Radially extending wings 314 and 316 have a substantially semi-circular shape and have a height which decreases from a first end to a second end of the implant. A series of holes 320 are formed in wing 316 and a throughbore 322 extends through cylindrical body portion 312. Each of holes 320 and throughbore 322 is configured to receive bone growth material, as discussed above. Alternately, holes 320 may be formed in both radially extending wings 314 and 316.

Referring to FIGS. 23-26, the intervertebral implant, shown generally as 400, may include a substantially conical body portion 412. See also FIGS. 16-18. Conical body portion 412 decreases in height from first end 418 to second end 420 of the implant.

Referring to FIGS. 27-31, the intervertebral implant, shown generally as 500, may include only one radially extending wing 514. The other radially extending wing 516 can be either partially or completely eliminated. As illustrated in FIGS. 27-30, radially extending wing 516 has been truncated. During a surgical procedure in which two intervertebral implants are implanted between adjoining vertebrae, the side of each implant having the truncated wing (or the side from which the implant has been eliminated) is positioned adjacent to the truncated wing of the other implant. See FIG. 31.

5                   FIG. 32 illustrates another embodiment of the intervertebral implant  
shown generally as 600. Intervertebral implant 600 includes a pair of cylindrical body  
portions 612a and 612b, a pair of radially extending wings 614 and 616, a central body  
10                   portion 618 and a throughbore 622. Throughbore 622 is centrally located in implant  
5                   600 and extends through a portion of both cylindrical body portions 612a and 612b. A  
single implant 600 can be used in surgical procedures which typically required two  
15                   intervertebral implants such as that shown in FIG. 31.

                  FIGS. 33-36 illustrate another embodiment of the intervertebral implant  
20                   shown generally as 700. Implant 700 includes a substantially cylindrical body portion  
10                   712 having a pair of radially extending semi-circular wings 714 and a throughbore 722.  
The top and bottom surfaces 724 and 726 of wings 714 are convex to conform to the  
25                   anatomical shape of the vertebral end plates. Alternately, the top and bottom surfaces  
of the wings may assume other shapes which conform to the shape of the vertebral  
30                   endplates. Implant 700 further includes a slot 750 and a threaded bore 752. Threaded  
15                   bore 752 extends from slot 750 into throughbore 722. Slot 750 and threaded bore 752  
are configured to engage an implant insertion tool (not shown) to facilitate insertion of  
35                   the implant into the intervertebral space. Although the slot and threaded bore are not  
shown in combination with the other implants disclosed in this application, it is  
40                   contemplated that each of the implants disclosed herein may include such insertion tool  
20                   engaging structure.

5                   It will be understood that various modifications may be made to the  
embodiments disclosed herein. For example, radially extending wings have been  
described as being tapered or angled along axis both parallel and transverse to the  
10                   longitudinal axis of the implant. Alternately, radially extending wings can be tapered  
5                   along any axis between the parallel and transverse axis. For example, radially  
extending wings 814 of implant 800 are tapered along an axis which forms an angle of  
15                   about 45° with respect to the longitudinal axis of the cylindrical body portion 812. See  
FIGS. 37 and 38. Moreover, the taper of the radially extending wings may be different  
20                   than that shown but should be such as to maintain the natural alignment of the  
10                   vertebrae. Alternately, radially extending wings need not be tapered. Therefore, the  
above description should not be construed as limiting, but merely as exemplifications of  
25                   preferred embodiments. Those skilled in the art will envision other modifications  
within the scope and spirit of the claims appended hereto.

## Claims

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WHAT IS CLAIMED IS:

1. An intervertebral implant comprising:

a first central body portion having a longitudinal axis; and

at least one wing extending radially outwardly from the central body

portion.

2. An intervertebral implant according to claim 1, wherein the at least

one radially extending wing has a height which decreases along the longitudinal axis of

the cylindrical body portion from one end of the cylindrical body portion to the other

end of the cylindrical body portion.

3. An intervertebral implant according to claim 2, wherein the

intervertebral implant includes two radially extending wings, each of the radially

extending wings having a shape substantially the same as the other radially extending

wing.

4. An intervertebral implant according to claim 1, wherein the at least

one radially extending wing has a height which decreases in a direction perpendicular to

the longitudinal axis of the cylindrical body portion.

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5. An intervertebral implant according to claim 4, wherein the intervertebral implant includes a pair of radially extending wings, wherein the smallest height of one of the radially extending wings being greater than the largest height of the other of the radially extending wings.

6. An intervertebral implant according to claim 1, wherein the implant is manufactured from bone.

7. An intervertebral implant according to claim 6, wherein the implant is manufactured from the diaphysis or the metaphysis of a long bone.

8. An intervertebral implant according to claim 7, wherein the intramedullary canal of the long bone defines the throughbore.

9. An intervertebral implant according to claim 1, wherein the implant is manufactured from a cortical ring cut from the diaphysis or metaphysis of a long bone.

10. An intervertebral implant according to claim 1, wherein the implant is manufactured from a biocompatible material.

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11. An intervertebral implant according to claim 1, further including protrusions formed on the surface of the intervertebral implant.

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12. An intervertebral implant according to claim 11, wherein the protrusions are formed on the at least one radially extending wing.

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13. An intervertebral implant according to claim 1, wherein the implant is formed from a bone derived composite material.

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14. An intervertebral implant according to claim 1, wherein the implant is formed from a bone derived layered material.

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15. An intervertebral implant according to claim 1, further including at least one opening formed in the at least one radially extending wing.

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16. An intervertebral implant according to claim 1, further including at least one throughbore defined in the central body portion, the throughbore having an axis which is substantially perpendicular to the longitudinal axis of the substantially cylindrical body portion.

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17. An intervertebral implant according to claim 1, further including a second central body portion having a longitudinal axis.

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18. An intervertebral implant according to claim 17, wherein the first and second central body portions have parallel longitudinal axis.

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19. An intervertebral implant according to claim 18, wherein the at least one radially extending wing includes two radially extending wings, one of the two radially extending wings extending outwardly from each of the first and second central body portions.

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20. An intervertebral implant according to claim 1, wherein the at least one radially extending wing includes two radially extending wings.

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21. An intervertebral implant according to claim 20, wherein each of the radially extending wings includes a top and a bottom surface, the top and bottom surfaces being shaped to conform to the shape of vertebral endplates.

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22. An intervertebral implant according to claim 22, wherein at least one of the top and bottom surfaces of the radially extending wings is convex.

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23. An intervertebral implant according to claim 1, further including engaging structure formed on the implant, the engaging structure being configured to receive an end of an implant insertion tool.

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24. A method for forming an intervertebral implant from the diaphysis or metaphysis of a long bone comprising the following steps:

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a. making a transverse cut across a long bone to form a cortical ring;

b. milling the top surface of the cortical ring to form a first

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longitudinally extending crown having two upper radially extending flats; and

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c. milling the bottom surface of the cortical ring to form a second

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longitudinally extending crown having two lower radially extending flats, the upper and lower flats forming a pair of radially extending wings.

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25. A method according to claim 24, wherein the first and second

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crowns are milled to form a substantially cylindrical body portion.

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26. A method according to claim 25, wherein the first and second

crowns are milled such that the intramedullary canal of the long bone extends through the substantially cylindrical body portion.

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27. A method according to claim 26, further including the steps of:

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milling the side surfaces of the cortical ring to form a substantially rectangular implant.

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28. A method according to claim 25, further including the step of  
5 milling the upper and lower radially extending flats to vary the angle of the flats in a  
15 direction parallel to the longitudinally extending axis of the substantially cylindrical  
body portion.

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29. A method according to claim 25, further including the step of  
10 milling the upper and lower radially extending flats to vary the angle of the flats in a  
25 direction transverse to the longitudinal axis of the cylindrical body portion.

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30. A method according to claim 24, further including the following  
step:

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d. forming protrusions on the intervertebral implant.

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31. A method according to claim 30, wherein the protrusions are  
formed on the radially extending wings.

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32. A method according to claim 24, wherein the first and second  
crowns are milled to form a substantially conical body portion.

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33. A method according to claim 24, further including the step of forming at least one hole in at least one of the radially extending wings.

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34. A method according to claim 24, wherein at least one of the upper and lower flats defining each of the radially extending wings is convex.

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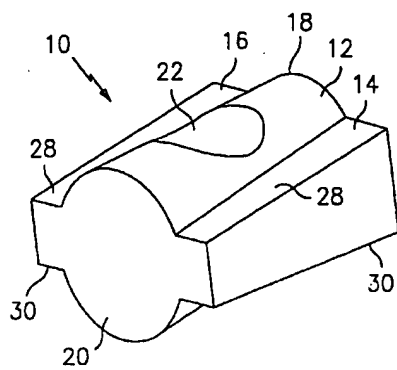


FIG. 1

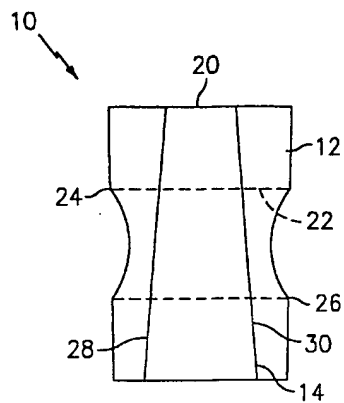


FIG. 2

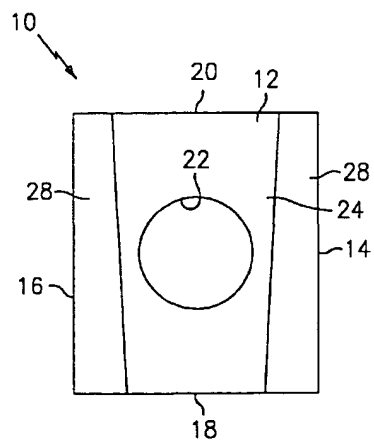


FIG. 3

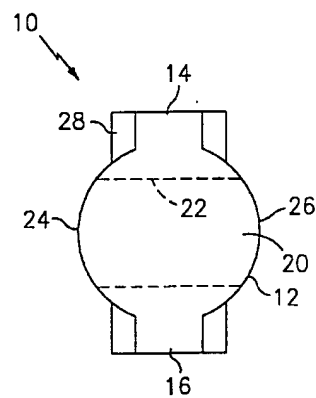


FIG. 4

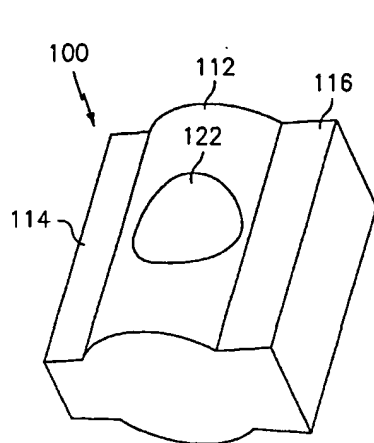


FIG. 5

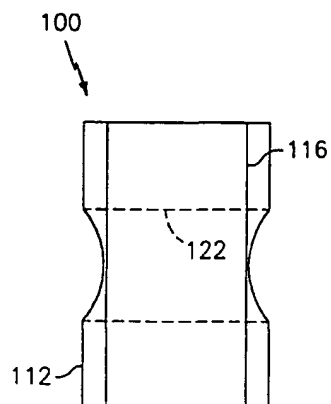


FIG. 6

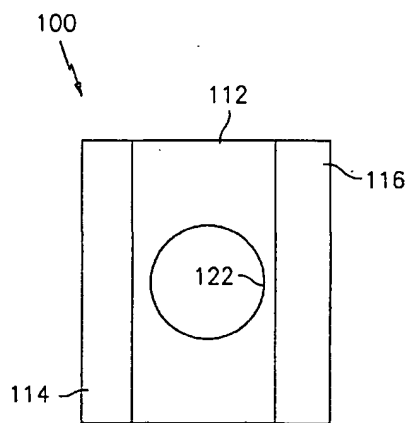


FIG. 7

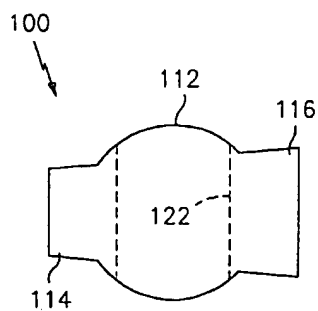
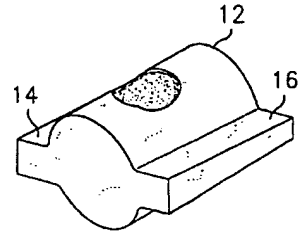
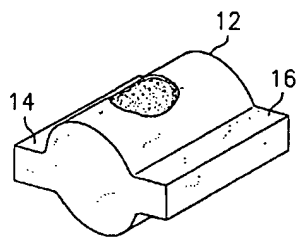
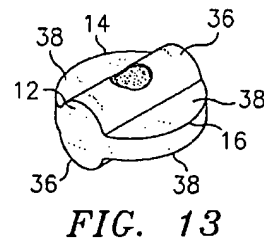
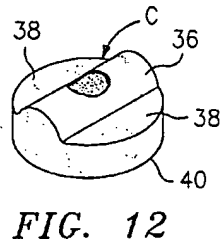
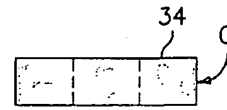
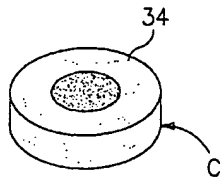
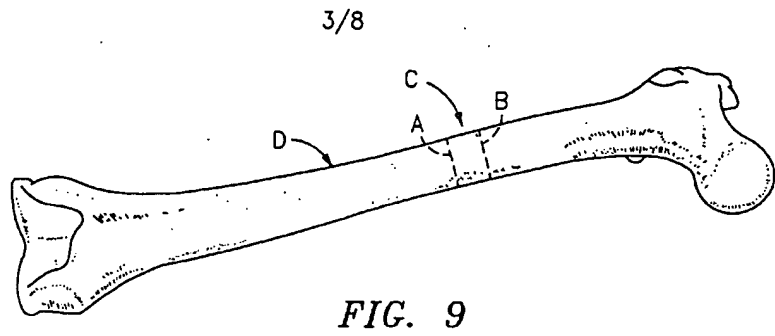


FIG. 8



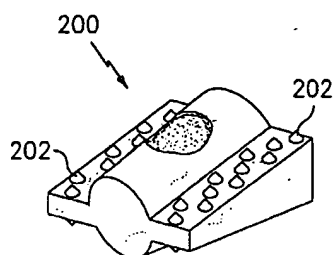


FIG. 16

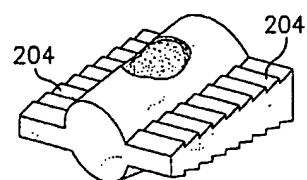


FIG. 17

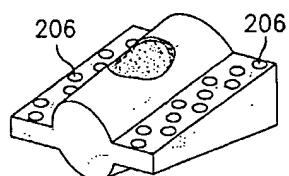


FIG. 18

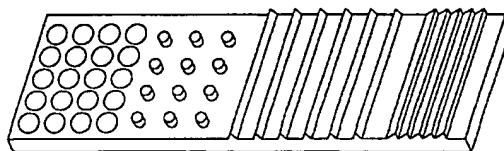


FIG. 18a

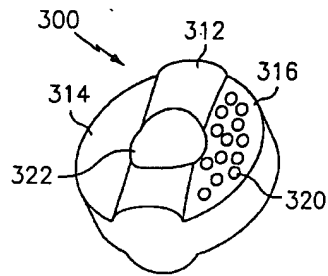


FIG. 19

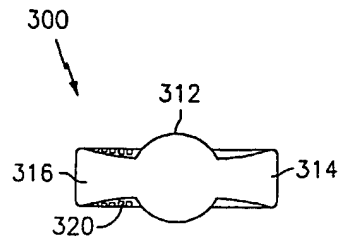


FIG. 20

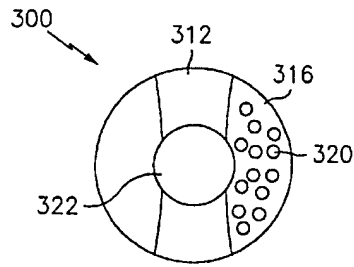


FIG. 21

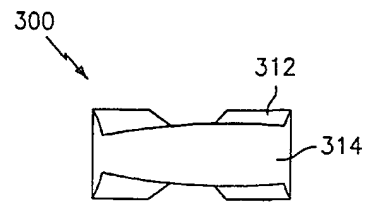


FIG. 22

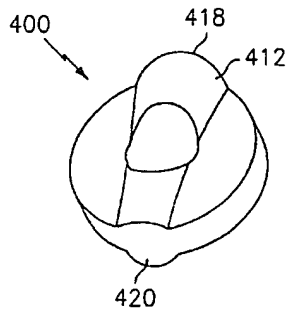


FIG. 23

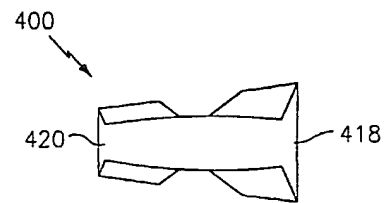


FIG. 24

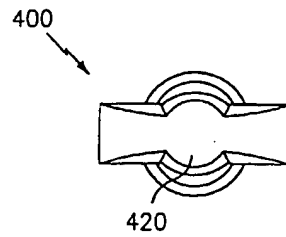


FIG. 25

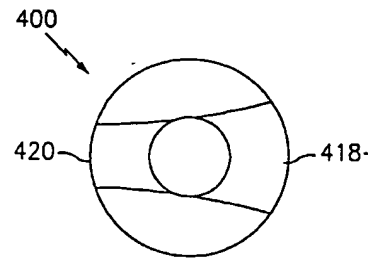


FIG. 26

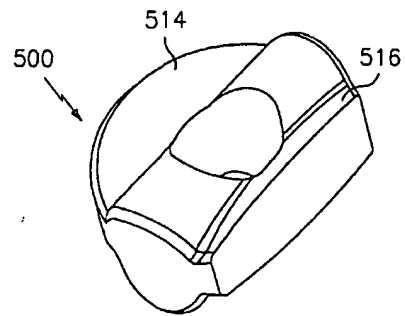


FIG. 27

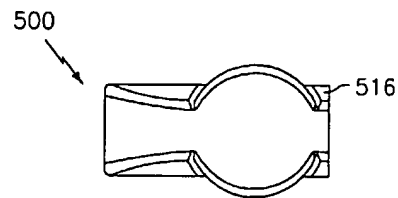


FIG. 28

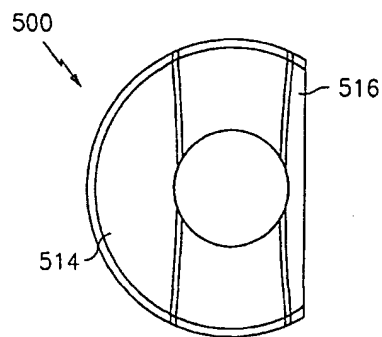


FIG. 29

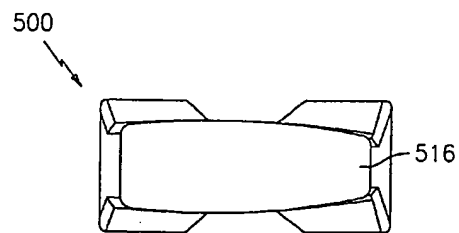


FIG. 30

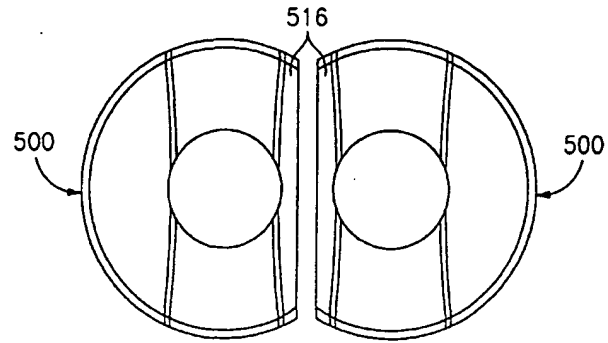


FIG. 31

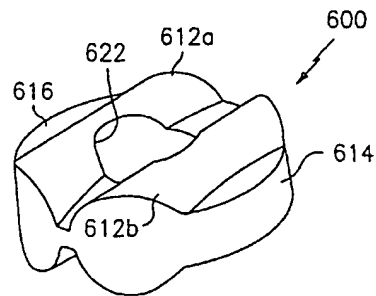


FIG. 32

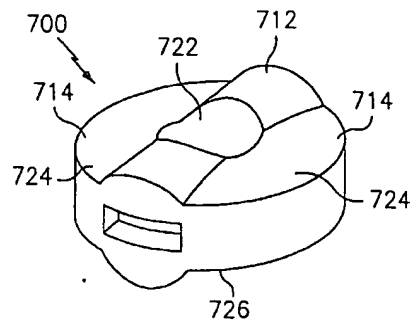


FIG. 33

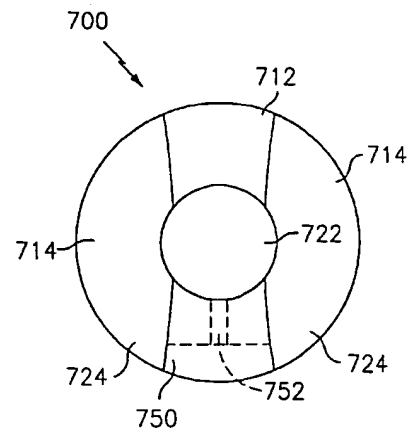


FIG. 34

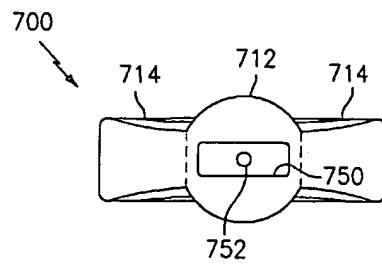


FIG. 35

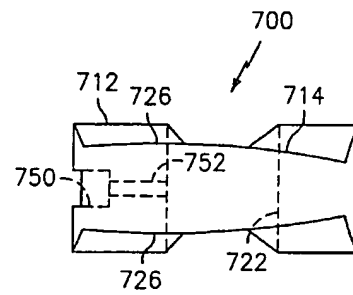


FIG. 36

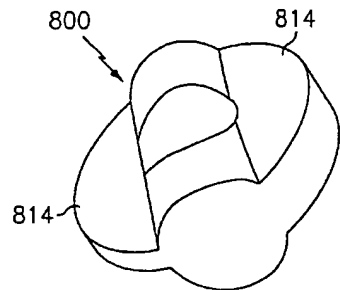


FIG. 37

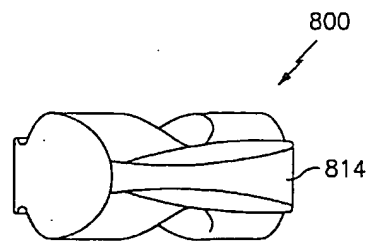


FIG. 38



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification: <b>A61F 2/44, A61F 2/46</b>	<b>A3</b>	(11) International Publication Number: <b>WO 00/42954</b> (43) International Publication Date: 27 July 2000 (27.07.2000)
(21) International Application Number: PCT/US00/01766 (22) International Filing Date: 24 January 2000 (24.01.2000) (30) Priority Data: 09/328,283      08 June 1999 (08.06.1999) US 60/116,852      22 January 1999 (22.01.1999) US (60) Parent Application or Grant OSTEOTECH, INC. [/]; (). SCARBOROUGH, Nelson, L. [/]; (). BOYLE, John, W. [/]; (). DILWORTH, Peter, G. ; ().	<b>Published</b>	
(54) Title: INTERVERTEBRAL IMPLANT (54) Titre: IMPLANT INTERVERTEBRAL  (57) Abstract <p>An intervertebral implant having a composite wedge/dowel configuration is provided. The intervertebral implant includes a central body portion and a pair of radially extending wings. The radially extending wings can be tapered from a first end of the implant to the second end of the implant along an axis parallel to the longitudinal axis of the central body portion. Alternately, the radially extending wings can be tapered along an axis transverse to the longitudinal axis of the cylindrical body portion or along any other axis between parallel and transverse to the longitudinal axis. A throughbore or plurality of throughbores extend from a top surface of the implant through the implant to a bottom surface of the implant. The implant may be formed from a cortical ring cut from the diaphysis of a long bone by milling the top and bottom surfaces of the cortical ring to form the substantially central body portion and the tapered radially extending wings. The cortical ring is milled such that the intramedullary canal of the cortical ring defines a throughbore in the central body portion of the implant. The sidewalls of the implant may be machined to form a substantially rectangular shape or the implant can be left to have a substantially circular configuration. Alternately, the implant may be formed of any biocompatible material having the requisite strength requirements via any known process, i.e., molding.</p> (57) Abrégé <p>L'invention concerne un implant intervertébral présentant une configuration de cale/tenon. Cet implant intervertébral comprend un élément central et deux ailes qui s'étendent dans une direction radiale. Ces ailes radiales peuvent s'effiler progressivement entre la première extrémité de l'implant et la seconde extrémité de l'implant le long d'un axe parallèle à l'axe longitudinal de l'élément central. Dans un autre mode d'exécution, les ailes radiales peuvent s'effiler le long d'un axe transversal à l'axe longitudinal de l'élément cylindrique ou le long d'un autre axe intermédiaire entre l'axe parallèle et l'axe transversal par rapport à l'axe longitudinal. L'implant est traversé par un ou plusieurs passages s'étendant entre la surface supérieure et la surface inférieure de l'implant. L'implant peut être formé d'un anneau cortical qu'on découpe dans la diaphyse d'un os long en fraisant les surfaces supérieure et inférieure de l'anneau cortical de manière à former l'élément sensiblement central et les ailes effilées radiales. On fraise l'anneau cortical de telle manière que le canal intramédullaire de l'anneau cortical définisse un passage traversant dans l'élément central de l'implant. On peut travailler les parois latérales de l'implant de manière à leur donner une forme sensiblement rectangulaire, ou bien on peut conserver la forme sensiblement circulaire de l'implant. Dans une forme d'exécution différente, l'implant peut être produit dans n'importe quel matériau biocompatible conforme aux exigences en matière de résistance, au moyen de n'importe quel procédé connu, p. ex. moulage.</p>		

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
27 July 2000 (27.07.2000)

PCT

(10) International Publication Number  
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(51) International Patent Classification<sup>7</sup>: A61F 2/44, 2/46

(21) International Application Number: PCT/US00/01766

(22) International Filing Date: 24 January 2000 (24.01.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/116,852 22 January 1999 (22.01.1999) US  
09/328,283 8 June 1999 (08.06.1999) US

(71) Applicant: OSTEOTECH, INC. [US/US]; 51 James Way, Eatontown, NJ 07724 (US).

(72) Inventors: SCARBOROUGH, Nelson, L.; 47 Lambert Johnson Drive, Ocean, NJ 07712 (US). BOYLE, John, W.; 10 Cornell Way, Upper Montclair, NJ 07043 (US).

(74) Agents: DILWORTH, Peter, G. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).

(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

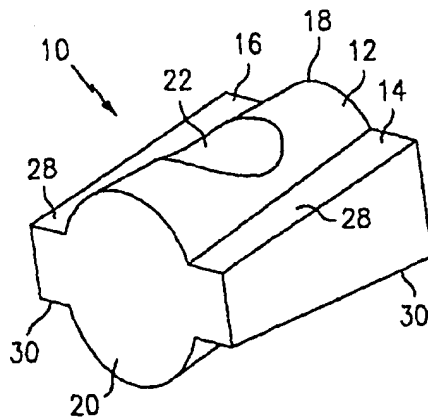
Published:

— With international search report.

(88) Date of publication of the international search report:  
30 November 2000

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTERVERTEBRAL IMPLANT



(57) Abstract: An intervertebral implant having a composite wedge/dowel configuration is provided. The intervertebral implant includes a central body portion and a pair of radially extending wings. The radially extending wings can be tapered from a first end of the implant to the second end of the implant along an axis parallel to the longitudinal axis of the central body portion. Alternately, the radially extending wings can be tapered along an axis transverse to the longitudinal axis of the cylindrical body portion or along any other axis between parallel and transverse to the longitudinal axis. A throughbore or plurality of throughbores extend from a top surface of the implant through the implant to a bottom surface of the implant. The implant may be formed from a cortical ring cut from the diaphysis of a long bone by milling the top and bottom surfaces of the cortical ring to form the substantially central body portion and the tapered radially extending wings. The cortical ring is milled such that the intramedullary canal of the cortical ring defines a throughbore in the central body portion of the implant.

The sidewalls of the implant may be machined to form a substantially rectangular shape or the implant can be left to have a substantially circular configuration. Alternately, the implant may be formed of any biocompatible material having the requisite strength requirements via any known process, i.e., molding.

WO 00/42954 A3

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 00/01766

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61F2/44 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 683 394 A (RINNER JAMES A) 4 November 1997 (1997-11-04) figures 1,3,4 column 2, line 54 -column 3, line 27 column 4, line 46 - line 50	1,10, 15-18,23
A	---	19-22
X	FR 2 742 652 A (COLORADO) 27 June 1997 (1997-06-27) figures 1-3 page 7, line 15 -page 8, line 3 claims 1-11	1,2,10
Y	---	6,7
Y	US 5 814 084 A (GRIVAS NICHOLAS E ET AL) 29 September 1998 (1998-09-29) figures 1-38 claims 1,16 ---	6,7
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

18 July 2000

Date of mailing of the international search report

26. 07 2000

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

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Mary, C

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# INTERNATIONAL SEARCH REPORT

Int. l. Application No.  
PCT/US 00/01766

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	FR 2 769 827 A (SDM) 23 April 1999 (1999-04-23) figures 5-8 page 4, line 31 -page 5, line 27 ---	1,4,5,10
E	US 6 045 580 A (MORRIS JOHN W ET AL) 4 April 2000 (2000-04-04) figures 18-30 column 4, line 37 - line 47 column 7, line 22 -column 8, line 51 ---	1
Y	---	28,29,32
P,X	WO 99 38461 A (SYNTHES AG ;SYNTHES USA (US)) 5 August 1999 (1999-08-05) figures 1-6 page 2, paragraph 2 page 3, paragraph 3 page 6, paragraph 2 -page 7, paragraph 2 page 8, paragraph 1 page 9, paragraph 1 - paragraph 3 page 10, paragraph 2 - paragraph 3 claims 1,2,5,15,22-25 ---	24,25, 30,31,34
Y	---	26-29,32
P,Y	WO 99 09914 A (CARTER KEVIN C ;GROOMS JAMIE M (US); SANDER TOM (US); DULEBOHN DAV) 4 March 1999 (1999-03-04) figures 1A-0,9,10A-16 page 9, line 14 -page 10, line 27 claims 1-14 claims 17-30 ---	26,27
A	US 4 950 296 A (MCINTYRE JONATHAN L) 21 August 1990 (1990-08-21) column 2, line 21 -column 3, line 22 figures 3,4 -----	24

# INTERNATIONAL SEARCH REPORT

i. national application No.  
PCT/US 00/01766

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-23

An intervertebral implant comprising a central body and at least one wing extending radially outwardly from the central body portion.

2. Claims: 24-34

A method for forming an intervertebral implant from the diaphysis or metaphysis of a long bone comprising a cutting and a milling step.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/01766

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5683394 A	04-11-1997	NONE	
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